

**AMENDMENTS TO THE CLAIMS**

1. (Currently Amended) A paste comprising bacterial cell wall skeleton components (bacteria-CWS) ~~which consists of a bacteria-CWS and an oil~~ wherein the paste has a viscosity of 0.7 poise or less (25 °C).

2. (Currently Amended) The paste comprising bacteria-CWS according to claim 1 wherein the paste has a viscosity between 0.2 and 0.7 poise ~~at 25 °C~~.

3. (CANCELLED).

4. (Currently Amended) The paste comprising bacteria-CWS according to ~~any one of claims 1 to 3~~ claim 1 wherein the bacteria-CWS is BCG-CWS.

5. (Currently Amended) The paste comprising bacteria-CWS according to ~~any one of claims 1 to 4~~ claim 1, wherein the oil is squalane.

6. (Currently Amended) The paste comprising bacteria-CWS according to claim 1, wherein the bacteria-CWS is BCG-CWS and wherein the paste comprises 6.6 g to 35.2 g of squalane per about 0.67 g of BCG-CWS.

7. (Original) A process for preparation of a paste comprising bacteria-CWS, which comprises the following steps:

- (1) a step of mixing the bacteria-CWS and oils in an organic solvent used as a dispersion-aiding solvent; and
- (2) a step of removing the organic solvent in (1) by distillation.

8. (Currently Amended) The process for preparation according to claim 177 wherein the organic solvent comprises a hydrocarbon solvent and a halogenated hydrocarbon solvent.

9. (Original) The process for preparation according to claim 8, wherein the organic solvent is a hydrocarbon solvent which comprises 5 to 20 % (v/v) of an alcohol solvent.

10. (Currently Amended) The process for preparation according to claim 8-~~or 9~~, wherein the hydrocarbon solvent is heptane or hexane.

11. (Currently Amended) A paste comprising bacteria-CWS obtainable obtained by the process for preparation according to any one of claims 7 to 10~~claim 7~~.

12. (CANCELLED)

13. (CANCELLED)

14. (Currently Amended) ~~The paste according to claim 1 that is formulated as an An oil-in-water emulsion which comprises the paste comprising bacteria-CWS according to any one of claims 1 to 6 and 11 to 13, and further comprises a surfactant, a stabilizer, and water.~~

15. (Currently Amended) ~~The oil-in-water emulsion paste~~ according to claim 14, which comprises 0.66 g to 3.35 g of the bacteria-CWS, and 0.4 wt% to 8 wt% of the oil per 2L of water.

16. (Currently Amended) The ~~oil in water emulsion paste~~ according to claim 14 or 15, wherein the stabilizer comprises 1 to 10 % mannitol.

17. (Currently Amended) The ~~oil in water emulsion paste~~ according to ~~any one of claims 14 to 16~~ claim 14, wherein the surfactant comprises 0.01 % to 3% polyethylenoxy sorbitan fatty acid ester.

18. (Currently Amended) The ~~oil in water emulsion paste~~ according to claim 17, wherein the polyethylenoxy sorbitan fatty acid ester is Tween 80.

19. (Currently Amended) The ~~oil in water emulsion paste~~ according to ~~any one of claim 14 to 18~~ claim 14, having the following properties:

- (1) the particle diameter of an oil droplet of the emulsion is 0.2 to 30  $\mu\text{m}$ ;
- (2) the bacteria-CWS is encapsulated in the oil droplet, and is negative for reaction with lectin.

20. (Currently Amended) A process for ~~preparation of the oil in water emulsion~~ preparing the ~~paste~~ according to ~~any one of claims 14 to 19~~ claim 14, which comprises the following steps:

(1) a step of emulsifying a mixture comprising the ~~paste~~ comprising bacteria-CWS according to any one of claims 1 to 10 and 17 to 19, and an aqueous solution containing a surfactant at a temperature higher than the turbidity point; and

(2) a step of adding an aqueous solution containing a stabilizer for dilution.

21. (Currently Amended) The process ~~for preparation~~ according to claim 20 wherein the ~~emulsification~~ emulsifying step in above step (1) comprises the following steps:

(3) a step of emulsifying a mixture comprising the paste comprising bacteria-CWS according to any one of claims 1 to 6 and 11 to 13, and an aqueous solution containing 0.02 % to 0.8 % of a surfactant (rough emulsification step); and

(4) a step of adding an aqueous solution containing a surfactant to the mixture of (3) to adjust the concentration of the surfactant, and vigorously stirring the mixture (complete emulsification).

22. (Currently Amended) A lyophilized formulation ~~obtainable~~ obtained by lyophilizing the emulsion according to ~~any one of claims 14 to 19~~ claim 14.

23. (CANCELLED)

24. (Original) An assembly of bacteria-CWS particles wherein the particle diameter is 0.15 to 6  $\mu\text{m}$  in the particle size distribution.

25. (Currently Amended) The assembly of bacteria-CWS particles according to claim 24, wherein the particle size distribution shows a single peak, as well as D10%:  $0.23 \pm 0.05 \mu\text{m}$  and D90%:  $0.60 \pm 0.05 \mu\text{m}$ .

26. (Currently Amended) A process for preparation of the assembly of bacteria-CWS particles according to claim 24-~~or~~ 25, which comprises dispersing the bacteria-CWS in a solvent containing an aliphatic hydrocarbon solvent.

27. (Original) The process according to claim 26, wherein the solvent is a mixture of an aliphatic hydrocarbon solvent and an alcohol solvent.

28. (Original) The process for preparation according to claim 27, wherein the solvent is a heptane containing 5 to 20 % ethanol.

29. (Currently Amended) A process for identification of a species and/or ~~strains~~-strain of a bacterium from which a bacteria-CWS is derived, which comprises the following steps:

(1) a step of separating and/or extracting the long-chain fatty acid contained in the bacteria-CWS to prepare a long-chain fatty acid fraction, and if necessary, converting the long-chain fatty acid in the long-chain fatty acid fraction into a derivative thereof;

(2) a step of determining the long-chain fatty acid or a derivative thereof in the long-chain fatty acid fraction of (1) by chromatography; and

(3) a step of identifying species and strains of a bacterium from which the bacteria-CWS is derived based on the results of determination (2).

30. (Currently Amended) The process according to claim 29 wherein step (1) comprises a step of labeling the long-chain fatty acid in the long-chain fatty acid fraction to prepare a labeled long-chain fatty acid derivative;—

31. (Currently Amended) A process for assay of the strength immunopotentiating activity of a bacteria-CWS, which comprises the following steps:

(1) a step of separating and/or extracting the long-chain fatty acid contained in the bacteria-CWS to prepare a long-chain fatty acid fraction, and if necessary, converting the long-chain fatty acid in the long-chain fatty acid fraction into a derivative thereof;

(4) a step of determining the content of the long-chain fatty acid or a derivative thereof in the long-chain fatty acid fraction; and

(5) a step of evaluating for an immunopotentiating activity of the bacteria-CWS based on the results of determination (4).

32. (Original) The process according to claim 31, wherein step (1) determining the content of the long-chain fatty acid or a derivative thereof comprises a step of labeling the long-chain fatty acid in the long-chain fatty acid fraction to prepare a labeled long-chain fatty acid derivative.

33. (Currently Amended) The process according to claim 30 or 32, wherein a derivative of the long-chain fatty acid is a long-chain fatty acid ester.

34. (Currently Amended) The process according to ~~any one of claims 29 to 33~~claim 29, wherein the bacteria are those of *Mycobacterium* or *Nocardia*.

35. (Original) The process according to claim 34, wherein the bacteria of *Mycobacterium* are those of BCG.

36. (Currently Amended) The process according to ~~any one of claims 29 to 35~~claim 29, wherein the long-chain fatty acid is mycolic acid.

37. (Currently Amended) The paste of claim 1 that is formulated as an assembly of bacteria-CWS particles comprising bacteria-CWS according to claims 1 to 6 and 11 to 13 which comprises an assembly of bacteria-CWS particles, wherein the particle diameter is from 0.1  $\mu\text{m}$  to 20  $\mu\text{m}$ , preferably from 0.15 to 6  $\mu\text{m}$ , and more preferably 0.2  $\mu\text{m}$  to 2  $\mu\text{m}$  in the particle size distribution.

38. (Currently Amended) The paste ~~comprising bacteria-CWS according to claim 37, wherein the assembly of bacteria-CWS particles exhibit a particle size distribution showing a single peak as well as D10%: 0.23 ± 0.05  $\mu\text{m}$  and D90%: 0.60 ± 0.05  $\mu\text{m}$ .~~

39. (Currently Amended) The paste according to claim 37 that is formulated as an An oil-in-water emulsion which further comprises the paste comprising bacteria-CWS according to claim 37 or 38, a surfactant, a stabilizer, and water.

40. (Currently Amended) The paste A lyophilized formulation obtainable by lyophilizing the emulsion according to claim 39 that is lyophilized.

41. (Currently Amended) A pharmaceutical composition ~~which consists of the comprising the emulsion according to any one of claims 14 to 19~~ claim 14 and 39.